4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 74

[Docket No. FDA-2017-C-2902]

Glo Eyes, LLC; Filing of Color Additive Petition

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of petition.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that we have filed a petition, submitted by Glo Eyes, LLC, proposing that the color additive regulations be amended to provide for the safe use of D&C Yellow No. 8 as a color additive in contact lens solution.

DATES: The color additive petition was filed on April 18, 2017.

FOR FURTHER INFORMATION CONTACT: Molly A. Harry, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240-402-1075.

SUPPLEMENTARY INFORMATION: Under section 721(d)(1) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 379e(d)(1)), we are giving notice that we have filed a color additive petition (CAP 7C0311), submitted by Glo Eyes, LLC, 5501 Highway 199, suite 202, Fort Worth, TX 76114. The petition proposes to amend the color additive regulations in 21 CFR part 74, Listing of Color Additives Subject To Certification, to provide for the safe use of D&C Yellow No. 8 (principally the disodium salt of fluorescein) as a color additive in contact lens solution.

We have determined under 21 CFR 25.32(l) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Dated: May 24, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

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